IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACCORD HEALTHCARE INC. and ACCORD HEALTHCARE INC. USA,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Purdue Pharma L.P. and Purdue Pharmaceuticals L.P. (collectively, "Purdue") and Rhodes Technologies ("Rhodes") (collectively, "Plaintiffs"), for their Complaint against Defendants Accord Healthcare Inc. and Accord Healthcare Inc. USA (collectively, "Accord" or "Defendants"), aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent Nos. 9,763,933 ("the Mannion '933 patent"); 9,775,808 ("the '808 patent"); 9,763,886 ("the '886 patent"); 9,073,933 ("the '933 patent"); 9,522,919 ("the '919 patent"); and 10,407,434 ("the '434 patent) (collectively, "the patents-in-suit"). This action relates to Abbreviated New Drug Application ("ANDA") No. 213564 submitted upon information and belief in the name of Defendants to the United States Food and Drug Administration ("FDA").

2. Plaintiffs seek judgment that Defendants have infringed the Mannion '933, '808, '933, '919 and '434 patents (collectively, "the Orange Book patents"), which are listed in the FDA *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book")

as covering Purdue's OxyContin® (oxycodone hydrochloride) ("OxyContin®"), an extended-release pain medication. Plaintiffs also seek judgment that Defendants have infringed the '886 patent. Defendants have infringed the Orange Book patents and the '886 patent at least under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 213564, submitted upon information and belief in the name of Defendants to the FDA. Defendants' ANDA seeks approval to market a generic version of Purdue's OxyContin®, which is the subject of approved New Drug Application ("NDA") No. 022272, in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg dosage strengths ("Defendants' ANDA Products").

THE PARTIES

3. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue Pharma is an owner of the Mannion '933, '808, '886, '933, '919, and '434 patents, identified in paragraphs 26-31 below. Purdue Pharma is also the holder of approved NDA No. 022272 for OxyContin®, indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Purdue Pharma sells OxyContin® in the United States.

4. Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of the Mannion '933, '808, '886, '933, '919, and '434 patents, identified in paragraphs 26-31 below.

5. Plaintiff Rhodes Technologies ("Rhodes") is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at

498 Washington Street, Coventry, RI 02816. Rhodes is an owner of the '933, '919 and '434 patents, identified in paragraphs 29-31 below, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in OxyContin®.

6. On information and belief, Defendant Accord Healthcare Inc. ("Accord Healthcare") is a company organized and existing under the laws of the State of North Carolina, having a principal place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

7. On information and belief, Defendant Accord Healthcare Inc., USA ("Accord USA") is a corporation organized and existing under the laws of the State of North Carolina, having a place of business at 1009 Slater Road, Suite 210-B, Durham, North Carolina 27703.

8. On information and belief, Defendants Accord Healthcare and Accord USA are both wholly-owned subsidiaries of Intas Pharmaceuticals Limited.

9. On information and belief, Defendants Accord Healthcare and Accord USA develop, manufacture, distribute and/or market pharmaceutical products throughout the United States, including in this judicial district, through their own actions and through the actions of their agents, including Accord USA acting as an agent for Accord Healthcare.

10. On further information and belief, Defendants Accord Healthcare and Accord USA are working in concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the Defendants' ANDA Products described in ANDA No. 213564.

11. On information and belief, Defendants Accord Healthcare and Accord USA closely coordinate their commercial activities and simultaneously share senior corporate officers.

12. On information and belief, Defendant Accord USA will distribute Defendants' ANDA Products when approved.

13. On information and belief, Defendants Accord Healthcare and Accord USA were jointly involved in the preparation and submission of Defendants' ANDA.

14. On further information and belief, if Defendants' ANDA is approved, Defendants Accord Healthcare and Accord USA will be jointly involved in the manufacturing, marketing, distributing and/or sale of Defendants' ANDA Products.

SUBJECT MATTER JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

17. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b). Defendants have also agreed not to challenge venue for the purposes of this action.

PERSONAL JURISDICTION

18. Defendants have agreed not to challenge personal jurisdiction for the purposes of this action.

19. Regardless, this Court has personal jurisdiction over each of the Defendants by virtue of, *inter alia,* their systematic and continuous contacts with Delaware and contacts with Delaware in connection with the submission of Defendants' ANDA, as set forth below.

20. On information and belief, Defendants are in the business of preparing generic pharmaceuticals that they distribute in the State of Delaware and throughout the United States.

21. On information and belief, if ANDA No. 213564 is approved, the Defendants' ANDA Products would, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware.

22. This Court further has personal jurisdiction over Defendants by virtue of the fact that they directed their "Notice of Paragraph IV Certification" to Plaintiffs, including Plaintiffs Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware, and Plaintiff Rhodes, which is a general partnership organized and existing under the laws of the State of Delaware.

23. This Court further has personal jurisdiction over Defendants by virtue of the fact that Defendants have committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs, including Plaintiffs Purdue Pharma and Purdue Pharmaceuticals, which are limited partnerships organized and existing under the laws of the State of Delaware, and Plaintiff Rhodes, which is a general partnership organized and existing under the laws of the State of Delaware.

24. This Court further has personal jurisdiction over Defendant Accord Healthcare because Defendant Accord Healthcare has been a defendant and counter claimant in several cases in this Court without challenge to the subject matter jurisdiction, venue or personal jurisdiction of this Court. For example, *Otsuka Pharmaceutical Co. et al. v. Accord Healthcare Inc.*, C.A. No. 19-1987-LPS (D. Del.), D.I. 9 (Accord Healthcare's 2/24/20 Answer, Affirmative Defenses And Counterclaims, Paragraphs 8, 9, and 13 ("Accord does not contest that subject matter jurisdiction is proper in this judicial district pursuant to 35 U.S.C. §§ 1331 and 1338(a) for purposes of this civil action only"; "Accord will not contest personal jurisdiction or venue in this

Court for purposes of this civil action only"; and "Accord will not contest personal jurisdiction in this Court for purposes of this civil action only.")); *Novartis Pharmaceuticals Corp. v. Accord Healthcare, Inc. et al.*, C.A. No. 18-1043-LPS (D. Del.), D.I. 46 (Accord Healthcare's 8/18/18 Answer To Complaint And Additional Defenses, Paragraphs 12, 13, 216 and 217 ("For purposes of this action only, Accord consents to jurisdiction and venue in the Court"; "For purposes of this action only, Accord does not contest [subject matter] jurisdiction or venue in this Court"; and "For the purpose of this action only, Accord does not contest personal jurisdiction over Accord")); and *Biogen International GmbH et al. v. Accord Healthcare Inc.*, C.A. No. 17-cv-872-LPS (D. Del.), D.I. 8 (Accord Healthcare's 10/16/17 Answer, Affirmative Defenses, And Counterclaims, Paragraphs 7, 1 [sic], and 3 [sic] (Accord "admits that this Court generally has subject matter jurisdiction over a civil action properly alleging infringement of a U.S. patent under 35 U.S.C. §§ 1331 and 1338(a)"; "does not contest venue or personal jurisdiction in this proceeding"; and "does not contest personal jurisdiction in this proceeding")).

25. This Court further has personal jurisdiction over Defendant Accord USA because Defendant Accord USA has been a defendant and counter claimant in several cases in this Court without challenge to the subject matter jurisdiction, venue or personal jurisdiction of this Court. For example, in *Pfizer Inc. et al v. Accord Healthcare Inc. USA*, C.A. No. 13-1155-GMS (D. Del.), Accord USA did not object to personal jurisdiction and venue in Delaware. *See* D.I. 9 (Accord USA's 8/21/13 Answer And Counterclaims, Paragraphs 6 and 7 ("Accord does not contest personal jurisdiction by this Court over Accord for purposes of this action only"; "Accord does not contest venue in this judicial district for purposes of this action only")).

THE PATENTS-IN-SUIT

26. Purdue is the lawful owner of all right, title and interest in the Mannion '933 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The Mannion '933 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the Mannion '933 patent is attached hereto as Exhibit A, which was duly and legally issued on September 19, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

27. Purdue is the lawful owner of all right, title and interest in the '808 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. The '808 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '808 patent is attached hereto as Exhibit B, which was duly and legally issued on October 3, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

28. Purdue is the lawful owner of all right, title and interest in the '886 patent, titled "TAMPER RESISTANT DOSAGE FORMS," including the right to sue and to recover for past infringement thereof. A copy of the '886 patent is attached hereto as Exhibit C, which was duly and legally issued on September 19, 2017, naming William H. McKenna, Richard O. Mannion, Edward P. O'Donnell, and Haiyong H. Huang as the inventors.

29. Purdue and Rhodes are the lawful owners of all right, title, and interest in the '933 patent, titled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE," including the right to sue and to recover for past infringement thereof. The '933 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '933 patent is attached hereto as Exhibit D, which

was duly and legally issued on July 7, 2015, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

30. Purdue and Rhodes are the lawful owners of all right, title, and interest in the '919 patent, titled "OXYCODONE COMPOSITIONS," including the right to sue and to recover for past infringement thereof. The '919 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '919 patent is attached hereto as Exhibit E, which was duly and legally issued on December 20, 2016, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

31. Purdue and Rhodes are the lawful owners of all right, title, and interest in the '434 patent, titled "PROCESS FOR PREPARING OXYCODONE COMPOSITIONS," including the right to sue and to recover for past infringement thereof. The '434 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '434 patent is attached hereto as Exhibit F, which was duly and legally issued on September 10, 2019, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

DEFENDANTS' ANDA

32. On information and belief, on or before August 25, 2020, Defendants filed Defendants' ANDA in the name of Defendants with the FDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Defendants' ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272.

33. On information and belief, Defendants subsequently submitted in their ANDA a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that, *inter alia*, the 'Mannion '933, '808, '933, '919 and '434 patents, listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272, are "invalid, unenforceable, and/or will not be infringed" by the commercial manufacture, use, offer for sale, sale or importation of the drug products described in Defendants' ANDA.

34. In a letter dated August 25, 2020, addressed to Plaintiffs and received by Purdue Pharma on or about August 26, 2020, Defendants provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendants' ANDA and Defendants' ANDA Products, and the Orange Book patents, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Notice Letter").

35. Defendants' submission of Defendants' ANDA was an act of infringement of the Orange Book patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

36. Plaintiffs commenced this action within the 45-day period after receiving the Notice Letter as described in 21 U.S.C. § 355(j)(5)(B)(iii).

FIRST CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,763,933)

37. Purdue incorporates by reference and reallege paragraphs 1 through 36 above as though fully restated herein.

38. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the Mannion '933 patent by Defendants.

39. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the Mannion '933 patent, including but not limited to

independent claims 1 and 11, which recite *inter alia*, a cured tablet comprising an extended release matrix, wherein said tablet comprises at least one polyethylene oxide having an approximate molecular weight of 1,000,000 to 15,000,000 and oxycodone, and various claims dependent therefrom.

40. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the Mannion '933 patent under 35 U.S.C. § 271(a)-(c). Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the Mannion '933 patent.

41. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the Mannion '933 patent.

42. Upon information and belief, Defendants have been aware of the existence of the Mannion '933 patent, and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the Mannion '933 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

43. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the Mannion '933 patent. Purdue does not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,775,808)

44. Purdue incorporates by reference and reallege paragraphs 1 through 36 above as though fully restated herein.

45. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '808 patent by Defendants.

46. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '808 patent, including but not limited to independent claims 1 and 11, which recite *inter alia*, a cured tablet comprising an extended release matrix, wherein said tablet comprises at least one polyethylene oxide having an approximate molecular weight of 1,000,000 to 15,000,000 and oxycodone, and various claims dependent therefrom.

47. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '808 patent under 35 U.S.C. § 271(a)-(c). Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '808 patent.

48. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '808 patent.

49. Upon information and belief, Defendants have been aware of the existence of the '808 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '808 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

50. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '808 patent. Purdue does not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,763,886)

51. Purdue incorporates by reference and realleges paragraphs 1 through 36 above as though fully restated herein.

52. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '886 patent by Defendants.

53. The manufacture of Defendants' ANDA Products, or the sale, offer for sale, or use thereof, are covered by one or more claims of the '886 patent, including but not limited to independent claim 1, which recites, *inter alia*, a method of producing a plurality of solid oral extended release pharmaceutical dosage forms comprising the steps of: mixing at least one active agent, at least one high molecular weight polyethylene oxide (PEO) having an approximate molecular weight of from 1 million to 15 million, to provide a PEO composition; compressing the PEO composition to provide a plurality of shaped matrix compositions; curing the shaped matrix compositions by exposure to heated air at a curing temperature that is at least the softening temperature of the high molecular weight PEO for a curing time of at least about 5 minutes, to provide a plurality of cured matrix compositions; cooling the cured matrix compositions; wherein (a) the molecular weight of each PEO is based on rheological measurements; (b) the high molecular weight PEO comprises at least about 30% (by weight) of each dosage form; (c) the total weight of each dosage form is calculated by excluding the combined weight of said film coatings; and (d) each cured matrix composition comprises a solid oral pharmaceutical dosage form that provides an extended release of at least one active agent, and various claims dependent therefrom.

54. If approved by the FDA, Defendants will infringe the '886 patent by making, using, offering for sale, selling, and distributing products embodying the patented

inventions in violation of 35 U.S.C. § 271(a) or (g) and/or by inducing others to make, use, sell, or offer for sale products and methods embodying the patented inventions in violation of 35 U.S.C. § 271(b).

55. Defendants, through at least their labeling and manufacturing process, will intentionally induce infringement of the '886 patent by at least patients who will take Defendants' ANDA Products, caregivers/healthcare providers who administer the products, and any manufacturers other than Defendants who manufacture Defendants' ANDA Products.

56. Upon information and belief, Defendants have been aware of the existence of the '886 patent and have no reasonable basis for believing that the manufacture, use, sale, or offer for sale of Defendants' ANDA Products will not infringe the '886 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

57. Unless Defendants are enjoined by the Court, Purdue will be substantially and irreparably harmed by Defendants' infringement of the '886 patent. Purdue does not have an adequate remedy at law.

FOURTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,073,933)

58. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 36 above as though fully restated herein.

59. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '933 patent by Defendants.

60. On information and belief, the process for making the oxycodone HCl API that Defendants intend to use in Defendants' ANDA Products is covered by one or more claims of the '933 patent, including but not limited to independent claim 10, which recites, *inter*

alia, a process of preparing an oxycodone hydrochloride composition having less than 25 ppm of 14-hydroxycodeinone, and various claims dependent therefrom.

61. If approved by the FDA, Defendants' importation, offer for sale, sale, and/or use of the oxycodone HCl API in Defendants' ANDA Products will infringe one or more claims of the '933 patent under 35 U.S.C. § 271(g).

62. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '933 patent, including but not limited to independent claims 1 and 16, which recite, *inter alia*, an oxycodone hydrochloride composition having less than 25 ppm of 14-hydroxycodeinone, and various claims dependent therefrom.

63. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '933 patent under 35 U.S.C. § 271(a)-(c). Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '933 patent.

64. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '933 patent.

65. Upon information and belief, Defendants have been aware of the existence of the '933 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '933 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

66. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants' infringement of the '933 patent. Purdue and Rhodes do not have an adequate remedy at law.

FIFTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,522,919)

67. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 36 above as though fully restated herein.

68. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '919 patent by Defendants.

69. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '919 patent, including but not limited to independent claims 1, 12 and 18, which recite, *inter alia*, an oxycodone hydrochloride composition having ratio of 8α,14-dihydroxy-7,8-dihydrocodeinone to oxycodone HCl is 0.04% or less as measured by HPLC, and various claims dependent therefrom.

70. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '919 patent under 35 U.S.C. § 271(a)-(c). Since at least the date of the Notice Letter, Defendants have acted with knowledge, or at least with willful blindness of the fact, that the induced acts would constitute infringement of the '919 patent.

71. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '919 patent.

72. Upon information and belief, Defendants have been aware of the existence of the '919 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '919 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

73. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants' infringement of the '919 patent. Purdue and Rhodes do not have an adequate remedy at law.

SIXTH CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 10,407,434)

74. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 36 above as though fully restated herein.

75. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 213564 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement of the '434 patent by Defendants.

76. On information and belief, the process for making the oxycodone HCl API that Defendants intend to use in Defendants' ANDA Products is covered by one or more claims of the '434 patent, including but not limited to independent claim 1, which recites, *inter alia*, a process of purifying oxycodone free base or oxycodone HCl that contains 8α, 14-dihydroxy-7,8-dihydrocodeinone ("8α") or HCl salt thereof, and various claims dependent therefrom.

77. If approved by the FDA, Defendants' importation, offer for sale, sale, and/or use of the oxycodone HCl API in Defendants' ANDA Products will infringe one or more claims of the '434 patent under 35 U.S.C. § 271(g).

78. Defendants' ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the '434 patent, including but not limited to dependent claim 20,

which recites, *inter alia*, purified oxycodone HCl prepared according to the process recited in dependent claim 2, which recites, *inter alia*, the process of independent claim 1 as well as specific ratios of 8α or HCl salt thereof to oxycodone free base or oxycodone HCl at certain stages in the claimed process.

79. If approved by the FDA, Defendants' commercial manufacture, use, importation, sale, and/or offer for sale of Defendants' ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '434 patent under 35 U.S.C. § 271(a)-(c).

80. Defendants' ANDA Products constitute a material part of the inventions covered by the claims of the '434 patent.

81. On information and belief, Defendants have been aware of the existence of the '434 patent and have no reasonable basis for believing that Defendants' ANDA Products will not infringe the '434 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

82. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants' infringement of the '434 patent. Purdue and Rhodes do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging that Defendants have infringed one or more claims of each of the Mannion '933, '808, '886, '933, '919, and '434 patents, and that the commercial sale, offer for sale, use, importation, and/or manufacture of Defendants' ANDA Products would infringe, induce

infringement of, and/or contribute to the infringement of one or more claims of each of the Mannion '933, '808, '886, '933, '919, and '434 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 213564 and Defendants' ANDA Products, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the last date of expiration of the Mannion '933, '808, '886, '933, '919, and '434 patents, plus any additional periods of extension or exclusivity attached thereto;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Defendants, their officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that is the subject of ANDA No. 213564, including Defendants' ANDA Products or any other drug product that infringes the Mannion '933, '808, '886, '933, '919, and '434 patents;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

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October 8, 2020